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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,544	03/19/2002	Laurent Di Costanzo	C1190/20009	7903

3000 7590 04/12/2007
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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/914,544

Applicant(s)

COSTANZO ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Vacation of Previous Action

The rejection that was mailed on 26 February 2007 was mistakenly indicated as a final rejection. This was a typographical error. The previous Office Action will now be vacated and will be replaced by this present Action.

Papers Received

Receipt is acknowledged of the applicant's information disclosure statement, received on 09 January 2006. Receipt is acknowledged of the applicant's request for continued examination, received on 04 October 2006. Receipt is acknowledged of the applicant's amendment and response, both received on 04 December 2006.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04 December 2006 has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 09 January 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 21-39 under 35 U.S.C. 103(a) as being unpatentable over Hunter *et al.* in view of Schmitz *et al.* and Valentine is maintained.

Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter *et al.* (U.S. Patent No. 6,391,337) in view of Schmitz *et al.* (U.S. Patent No. 6,079,968)

The Hunter *et al.* patent teaches pharmaceutical dosage forms for a rapidly disintegrating tablet (See Column 5, Lines 27-45; Example 8; and Figure 3). Processes for making this tablet are disclosed (See Column 2, Line 52 to Column 3, Line 55). The tablets can variously comprise saccharides as inert fillers, including sucrose, dextrose, lactose, xylitol, fructose, and sorbitol (See Column 12, Lines 1-13). A lubricant, such as magnesium stearate, can be included in the tablets in amounts ranging from 0.01% to 4.0% by weight of the dosage form (See Column 10, Lines 1-23). A disintegrant may be included as well, such as sodium starch glycolate and cross-linked polyvinyl pyrrolidones (See Column 11, Lines 52-67). Other additives may also be

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included as well, such as flavorants, sweeteners, and coloring agents (See Column 15, Lines 41-53). The dosage forms are prepared by direct compression of a dry granulate (See Claim 1).

The Hunter *et al.* patent does not explicitly teach methods of manufacturing tablets wherein the lubricant is entirely or mostly applied to the outer surface of the tablet.

The Schmitz *et al.* patent discloses a device that sprays powdered lubricants onto punches and dies of a tablet press. Such a device can be readily retrofitted into existing machinery and provide an improved method of tablet manufacture (See Column 1, Line 35 to Column 3, Line 36).

It would be obvious to one of ordinary skill in the art to combine the teachings of the Hunter *et al.* and Schmitz *et al.* into the objects of the instantly claimed invention. One of ordinary skill in the art would be motivated to combine the Hunter *et al.* and Schmitz *et al.* references to create an improved process of making pharmaceutical dosage forms that meters out tablet lubricants in a more efficient manner in such a way that minimizes caking of lubricants onto tablet dies. As is been disclosed that the device disclosed in Schmitz *et al.* can be readily retrofitted into existing machinery, it is the position of the examiner that the two references can be combined by one of ordinary skill in the art with a reasonable expectation of success. As stated above, the Valentine reference is relied upon as a teaching reference solely with respect to what is known about the particles sizes of lubricants within the art.

Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed on 04 December 2006 have been considered but are not considered persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Much of the applicant's arguments are directed toward the disclosure in the Hunter *et al.* reference where lubricant is added to the tablet mixture before it is pressed into tablets, stating that because of this disclosure, the prior art rejection of record does not render the instantly claimed invention obvious. Further, the applicant also argues that the combined disclosures of the prior art would not lead one of ordinary skill in the art to practice the instantly claimed invention. However, this argument is flawed.

The primary purpose of the inclusion of a lubricant in a tablet is to allow a compressed tablet to properly disengage from a press or die. If a prior art modification allows one of ordinary skill in the art to coat a tablet press with lubricant, then it should follow that one of ordinary skill in the art would see the inclusion of lubricant in the tablet mixture itself to be redundant and would thus remove it from the tablet mixture. Therefore, it is the position of the examiner that one of ordinary skill in the art would combine the prior art references to produce a tablet where the lubricant is located on the outer surface of each tablet, thus reading on the limitations of the instant claims. As such, all pending claims remain rejected.

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Correspondence

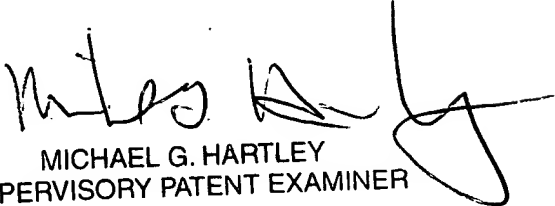
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sj0


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER